In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-397V

Filed: December 28, 2022

RAYMOND MARKARIAN,	*	TO BE PUBLISHED
Petitioner,	*	Ruling on the Record;
v.	*	Tetanus Diphtheria Acellular-Pertussis
	*	(Tdap) Vaccine; Shoulder Injury Related
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	To Vaccine Administration (SIRVA);
	*	Brachial Neuritis
Respondent.	*	

Bridget McCullough, Esq., Muller Brazil, LLP, Dresher, PA, for petitioner.
Claudia Gangi, Esq., U.S. Department of Justice, Washington, DC, for respondent.

RULING ON THE RECORD[1]

Roth, Special Master:

On March 15, 2018, Raymond Markarian ("Mr. Markarian" or "petitioner") filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner alleges he suffered "Parsonage Turner Syndrome resulting from the adverse effects of the TDaP vaccination" received on November 11, 2016. *See* Petition, ECF No. 1. An amended petition was filed on June 11, 2018, alleging that petitioner suffered "brachial neuritis caused-in-fact by the TDaP vaccination (an 'off-Table' injury), received on November 11, 2016." Amended Petition, ECF No. 17. Respondent filed his Rule 4(c) Report on April 22, 2019, stating that this matter was not appropriate for compensation. Resp. Report, ECF No. 27.

[1] This Ruling has been designated "to be published," which means I am directing it to be posted on the Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id*.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petitioner filed a motion for ruling on the record on December 11, 2020. Motion for Ruling on the Record ("Motion"), ECF No. 46. On January 25, 2021, respondent filed a response to petitioner's motion. Response, ECF No. 48. Petitioner filed a reply on February 24, 2021. Reply, ECF No. 52.

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner has provided preponderant evidence that his Tdap (Tetanus/diphtheria/acellular pertussis) vaccination caused him to suffer brachial neuritis, satisfying petitioner's burden of proof under *Althen v. Secretary of Health and Human Service*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

I. Background and Factual History

A. Procedural History

The petition was filed on March 15, 2018, alleging that petitioner suffered from Parsonage Turner Syndrome, also known as brachial neuritis, as a result of the Tdap vaccine he received on November 11, 2016. Petition, ECF No. 1. Petitioner also filed medical records and an affidavit on March 15, 2018. Petitioner's Exhibits ("Pet. Ex.") 1–4, ECF No. 1. On March 19, 2018, the petition was assigned to the Special Processing Unit ("SPU"). Initial Order at 1–4, ECF No. 5. Petitioner continued to file medical records until May 17, 2018. Pet. Ex. 5, ECF No. 14. Petitioner filed a statement of completion that same day. ECF No. 15.

An amended petition was filed on June 11, 2018, alleging that petitioner's brachial neuritis was "caused-in-fact by" the Tdap vaccine. Amended Petition, ECF No. 17. After several status reports requesting additional time to review the medical records, respondent advised that he would be defending this case. Resp. S.R. at 1, ECF Nos. 19, 21, 24. A government shutdown was in effect from December 22, 2018 until January 25, 2019.

Respondent filed his Rule 4(c) Report on April 22, 2019, stating that this matter was not appropriate for compensation. Resp. Report, ECF No. 27. Petitioner was ordered to file an expert report addressing the issues raised in respondent's Rule 4(c) Report. Scheduling Order at 1, ECF No. 28.

On November 4, 2019, petitioner filed an expert report from Dr. Naveed Natanzi with supporting literature. Pet. Ex. 6–25, ECF No. 33. On March 27, 2020, respondent filed an expert report from Dr. Thomas P. Leist with supporting medical literature. Resp. Ex. A, Tabs 1–5, B, ECF No. 37.

On April 20, 2020, this case was assigned to the undersigned. Notice of Assignment, ECF No. 39. At a status conference held on May 28, 2020, a review of petitioner's medical history and the parties' expert reports were discussed. Petitioner was to submit a demand for respondent's consideration. Scheduling Order at 1–2, ECF No. 40. Petitioner confirmed his submission of a demand to respondent by status report filed on July 19, 2020. Pet. S.R., ECF No. 41. On August

19, 2020, respondent filed a status report stating he considered the demand but was not interested in pursuing settlement. Resp. S.R. at 1, ECF No. 42.

On September 30, 2020, petitioner filed a status report advising that he would like to proceed with a ruling on the record. Pet. S.R., ECF No. 43. Petitioner filed his motion for ruling on the record on December 11, 2020, alleging that he suffered from both SIRVA and brachial neuritis. Motion, ECF No. 46. Respondent filed a response on January 25, 2021, maintaining that petitioner had not met his burden regarding either injury alleged. Response, ECF No. 48. Petitioner filed a reply on February 24, 2021. Reply, ECF No. 52.

I have determined that the parties have had a full and fair opportunity to present their cases, and I agree with the parties that this matter can be resolved on the record without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearings and those decisions were upheld). "Special masters must determine that the record is comprehensive and fully developed before ruling on the record." *Kreizenbeck*, 945 F.3d at 1366. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of a hearing has been affirmed on appeal. I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that the special master acted within his discretion in denying an evidentiary hearing); *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

Accordingly, this matter is now ripe for resolution.

B. Medical Terminology

Prior to discussing the case at hand, a brief explanation of the medical conditions mentioned throughout this Ruling is necessary.

Acute brachial neuritis ("BN") is a distinct plexus disorder. It is known by many names, including brachial plexus neuropathy, local neuritis of the shoulder girdle, acute brachial plexitis, acute shoulder neuritis, paralytic neuritis, and Parsonage Turner Syndrome. Pet. Ex. 18.[3] Viral etiology has been proposed; studies show that infection precedes onset in as many as 25% of cases and up to 15% of cases follow vaccination. *Id.* But "[w]hether an injection injury to a peripheral nerve is caused by direct injury to the nerve or secondary to chemical insult is unclear." Pet. Ex. 23 at 3.[4] The imaging in a case study filed by petitioner suggested that the "nerve injury was caused

[3] Jimmy D. Miller, M.D. et al., *Acute Brachial Plexus Neuritis: An Uncommon Cause of Shoulder Pain*, 62 AM. FAMILY PHYSICIAN 2067 (2000), filed as "Pet. Ex. 18."

[4] Pedro K. Beredjiklian, M.D. et al., *Isolated Radial Nerve Palsy Secondary to Influenza Vaccination: A Case Report with Imaging Correlation*, PRACTICAL NEUROLOGY (2012), filed as "Pet. Ex. 23."

by injection of the vaccination into the nerve sheath and not the nerve itself. . . The etiology of injury—direct trauma to the nerve versus indirect injury via an inflammatory process—" was also unclear. *Id.*

BN presents with severe, acute, burning pain in the shoulder and upper arm with no apparent cause. Pet. Ex. 18 at 2.[5] It may awaken a patient from sleep. *Id.* In most, the pain subsides over the following days to weeks, resulting in a subsequent weakness in the upper arm—at times to the point of muscle flaccidity. *Id.*; *see also* Pet. Ex 19 at 2;[6] Pet. Ex. 20 at 1.[7] This temporal profile of initial arm and shoulder pain followed by muscle weakness as the pain subsides is an important characteristic of acute brachial plexus neuritis. *Id.*

The brachial plexus is a network of nerves with its lymphatic system and blood vessels "originating from the anterior rami of spinal nerves C5-8 and T1. Situated partly in the neck [] and partly in the axilla."[8] It is subdivided into "5 anterior rami, 3 trucks [], 6 divisions [], and 3 cords," and has numerous branches. *Id.* The usual abnormality evident on physical examination is one of a brachial plexus lesion, as indicated by involvement of two or more nerves. Pet. Ex. 18 at 2.[9] Weakness is commonly in the supraspinatus, infraspinatus, deltoid and/or bicep muscles usually involving the upper plexus. *Id.*

Diagnostic evaluation for BN includes magnetic resonance image ("MRI"), which may show high signal abnormality of affected muscles, or electromyography ("EMG"), which will localize the lesion to the brachial plexus and will reveal fibrillation potentials and positive waves suggestive of muscle denervation around three weeks following onset. Pet. Ex. 18 at 3.[10] But nerve conduction studies ("NCS") of the medial and ulnar nerves are generally within normal limits in a patient with BN. *Id.*

Treatment of BN includes analgesics, sometimes narcotics (such as hydrocodone), and physical therapy. Pet. Ex. 18 at 3.[11] Corticosteroids may also be used, but they have not shown any "proven benefit." *Id.* In most patients, recovery of muscle strength occurs within roughly 3 months with complete resolution in 89% of patients within 3 years; however, some patients will unfortunately have permanent weakness. Pet. Ex. 19 at 2.[12]

Cervical radiculopathy, unlike BN, presents with pain beginning in the neck area and radiating down the arm for variable distances. Pet. Ex. 18 at 2.[13] Patients with cervical radiculopathy may awaken in the morning with pain but have no obvious preceding etiology. *Id.*

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[5] Miller, M.D. et al., *supra* note 3.
[6] Maliha Farhana Shaikh et al., *Acute Brachial Neuritis Following Influenza Vaccination*, BMJ CASE REP. (2012), filed as "Pet. Ex. 19."
[7] John S. Taras et al., *Brachial Neuritis Following Quadrivalent Human Papilloma Virus (HPV) Vaccination*, 6 HAND 454 (2011), filed as "Pet. Ex. 20."
[8] Dorland's Illustrated Medical Dictionary 1440 (33d ed. 2019).
[9] Miller, M.D. et al., *supra* note 3.
[10] *Id.*
[11] *Id.*
[12] Shaikh et al., *supra* note 6.
[13] *Id.*

The pain is associated with partial weakness in the muscles supplied by the involved nerve root and sensory loss in the appropriate dermatome. *Id*. Unlike BN, the pain, weakness, and sensory loss associated with cervical radiculopathy tends to occur simultaneously. *Id.* Additionally, BN involves multiple nerves of the brachial plexus, while radiculopathy, by definition, is restricted to one nerve root. *Id.*

C. Shoulder Injuries Defined by the Vaccine Program

Brachial neuritis occurring within 2 to 28 days after tetanus toxoid vaccines is a covered condition by the Vaccine Act, as set forth on the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(I)(B). A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests the following:

(i) Pain in the affected arm and shoulder is a presenting syndrome and occurs within the specified time-frame;
(ii) Weakness;
(A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in the muscles supplied by more than one peripheral nerve.
(B) NCS and EMG studies localizing the injury to the brachial plexus are required before the diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve.
(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and
(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

42 C.F.R. 100.3(c)(6) (2017).

Shoulder injury related to vaccine administration is another listed injury on the Vaccine Injury Table. 42 C.F.R. 100.3(a)(I)(C) (2017). The Table states that SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. 42 C.F.R. 100.3(c)(10) (2017). SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). *Id.* As defined by the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests the following:

(i) No history of pain, inflammation, or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
(ii) Pain occurs within specified-time frame;
(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. 100.3(c)(10) (2017).

D. Medical History

1. Petitioner's Medical History Prior to the Allegedly Causal Tdap Vaccination

Petitioner's prior medical history was non-contributory. He was a carpenter with associated arthralgias from physical labor over the years. Pet. Ex. 2 at 52. Petitioner had no history of neurological injury or disease and no musculoskeletal or left shoulder pain or injury. *Id.* at 23.

On November 11, 2016, petitioner presented to Dr. Jarrett Gavin Williams at Santa Clarita Medical Office for lower left abdominal pain that had been progressively getting worse for three weeks. Pet. Ex. 2 at 182. His mother had been diagnosed with cancer three weeks earlier and he believed his symptoms were stress related. *Id.* at 184. His physical examination was normal, and he was noted to be a "healthy adult." *Id.* at 183–87. He deferred medication for his stomach because his discomfort was not severe. *Id.* at 187. His record included discontinued medications prescribed in the past, including Cipro and cholecalciferol. *Id.* at 201. X-ray of his abdomen on that date was documented with "[N]o worrisome findings on xr" and was compared to those from 2014. *Id.* at 187; 191-92. Petitioner had no neurological complaints and no signs of fever. *Id.* at 184-85. Dr. Williams noted petitioner to be pre-diabetic and to have a vitamin D deficiency. *Id.* at 184. Petitioner declined the flu vaccine during this visit, but the subject Tdap vaccination was administered. *Id.* at 182–85, 192.

2. Petitioner's Medical History Following the Allegedly Causal Tdap Vaccination

On November 12, 2016, at 1:53am, petitioner presented to Panorama City Hospital Emergency Department ("ED") complaining of arm pain. Pet. Ex. 2 at 211. He reported receipt of a Tdap vaccine at 9am the morning of November 11, 2016, went to bed that evening around 9-10pm and awoke at 12:30am with shaking, chills, numbness, and tingling in the left hand and weakness in the left arm that had worsened. *Id.* at 212. At the hospital, he was unable to lift his left arm. *Id.* He also reported light headedness and a headache. *Id.* At around 2:30am, petitioner experienced tingling of the left side of his face and body. *Id.* at 213. He had pain with range of motion of the left arm at the deltoid, acute tenderness to palpation over the injection site with no visible swelling and mild palpable firmness. *Id.* at 214. His left fingers were cool to the touch compared to the right with slight erythema. *Id.* He was positive for rash and myalgias but had no joint pain or fever. *Id.* at 262. He also had significant weakness in his left radial, median, and ulnar nerves. *Id.* at 214. The ED doctor, Dr. Linda Szema, initially thought petitioner was having a stroke, but electrocardiogram ("EKG") and computerized tomography ("CT") scans were negative/normal. *Id.* at 232-34. A Telemedicine visit with neurologist Dr. Rita Ceponiene ruled out stroke with neurological symptoms thought to be due to pain. *Id.* at 217, 220. Dr. Ceponiene noted that "[a]cute demyelinating plexopathy or acute immune – mediated encephalomyelitis are

(sic) unlikely given the immediate time line post vaccination." *Id.* at 225. Dr. Szema's impression was possible SIRVA or BN from Tdap vaccination. *Id.* at 218*; see also* Pet. Ex. 5.

Petitioner followed up that day, November 12, 2016, with Dr. David Wong for left arm pain following the Tdap vaccine. Pet. Ex. 2 at 260. Dr. Wong's primary encounter diagnosis was "adverse drug reaction." *Id.* at 263.

It was noted at a follow up examination on November 14, 2016, that the ED doctors believed petitioner's symptoms to be muscle spasms from the tetanus vaccine. Pet. Ex. 2 at 284.

Petitioner's primary care physician ("PCP") referred him for a neurological consultation with Dr. Marika Issakhanian on November 15, 2016 due to continuing numbness, lack of sensation in his left hand, and difficulty lifting his left arm. Pet. Ex. 2 at 296–302. He reported receipt of a Tdap vaccine with almost immediate pain at the injection site. *Id.* at 297. The pain worsened awaking him from sleep, which prompted him to go to the ED. *Id.* The pain improved the next day, but the numbness and difficulty lifting his arm continued. *Id.* The numbness radiated from his upper arm down to his fingers and he could not raise his left arm. *Id.* His main complaints included some pain in the deltoid and lack of sensation in the left hand mainly in the small, ring, and middle fingers with some involvement of the second digit. *Id.* He reported a prior tetanus shot while in the military without issue but believed it was given in the buttocks. *Id.* Dr. Issakhanian, along with a colleague with expertise in neuromuscular disorders and EMG, evaluated petitioner. *Id.* at 300. The impression was weakness of the left arm with distribution "beyond a single nerve injury or even radiculopathy," with symptoms "more consistent with brachial plexus issue" not suspected to be due to trauma from the injection but rather related to an autoimmune reaction to the vaccine. *Id.* An EMG was discussed, as was occupational therapy ("OT") and a trial of steroids. *Id.* Petitioner did not want to pursue any treatment at that time because he was caring for his mother throughout her chemotherapy. *Id.*

During a telemedicine visit with Dr. Issakhanian on November 22, 2016, petitioner complained of pain and weakness when he tried to lift his left arm sideways. Pet. Ex. 2 at 308. He continued to have numbness in the tips of his fingers, and his arm and hand would become stiff when he did not use them. *Id.*

At a December 1, 2016 follow up telemedicine visit, petitioner reported that he was unable to see the in-network physical therapist because they were not flexible with scheduling, so he asked for an in-network chiropractor. Pet. Ex. 2 at 313.

On December 7, 2016, petitioner advised Dr. Issakhanian by phone that he was doing exercises on his own but was not sure he was doing them correctly. Pet. Ex. 2 at 324. It was still difficult to feel his left fingers. *Id.* The doctor discussed medications for neuropathic pain, an MRI with contrast, NCS/EMG testing, physical therapy, and steroids with petitioner. *Id.* Petitioner was also cautioned about the importance of avoiding a frozen shoulder. *Id.* He expressed a willingness to try Neurontin (gabapentin) for neuropathic pain but wanted a second opinion before undergoing any testing. *Id.* Petitioner advised that he was unable to do the physical type of work that he used to. *Id*. The impression was Parsonage Turner Syndrome or brachial plexus injury. *Id.*

When petitioner presented for occupational therapy on December 12, 2016, he had decreased range of motion, grip strength, and pinch strength. Pet. Ex. 2 at 351. He reported trouble with activities of daily living including dressing, bathing, grooming, functional mobility and transfers, vacuuming, and cooking. *Id.*

On December 21, 2016, petitioner reported taking Neurontin at night, but the pain relief effect wore off by mid-day. Pet. Ex. 2 at 368. The Neurontin was increased to twice a day—once in the morning and once at night. *Id.* at 368, 370.

At his December 27, 2016 visit to OT, petitioner reported left arm and hand weakness, numbness, and severe pain in the left shoulder after a tetanus shot, although the pain was improving. Pet. Ex. 2 at 373, 375. Petitioner also reported stiffness in the morning and use of heat for relief. *Id.* at 375. By January 3, 2017, petitioner reported feeling a little better and was trying to complete the prescribed exercises. Pet. Ex. 2 at 381.

Petitioner complained of increased pain on January 9, 2017, after trying to vacuum. Pet. Ex. 2 at 387. On January 31, 2017, he reported continued left arm and hand weakness, numbness, and pain after the tetanus shot. *Id.* at 398.

On February 7, 2017, while participating in rehabilitation for his wrist and hand, petitioner reported weakness of his left arm and pain in his left bicep, but his left shoulder felt 20-25% better since his last visit. Pet. Ex. 2 at 406-08.

On February 16, 2017, petitioner presented for OT with pain in his upper arm and his "only problem is lifting [his] arm up." Pet. Ex. 2 at 416. Petitioner continued to note shoulder problems, including decreased range of motion, grip strength, and pinch strength at his February 21, 2017 OT visit. *Id.* at 423.

At a March 1, 2017 visit, petitioner reported continued but improved numbness in his small, ring, and middle finger. Pet. Ex. 2 at 436. During his March 16 and March 23, 2017 visits, petitioner reported left shoulder pain and "stabbing" left shoulder pain, respectively. *Id.* at 457. By March 30, 2017, however, he reported that the pain was not as bad. *Id.* at 464. He had been using weights with no problem and was doing some resisted shoulder exercises using a bottle of water. *Id.* He wanted to return to archery. *Id.*

On April 25, 2017, petitioner reported weakness in his left hand, but his sensory and focal weakness was much improved. Pet. Ex. 2 at 483. He was continuing with OT and working hard on his own to improve his strength. *Id.* at 484. At his neurology follow up on April 25, 2017, Parsonage Turner and autoimmune reaction to injection were listed in the differential. *Id.* at 483. An EMG and steroids were again discussed, but petitioner declined additional testing and treatment because he had some improvement and was busy taking care of his mother. *Id.* He reported being able to hold his bow in his left arm, but pain limited his ability to use the bow effectively. *Id.* at 484. He reported that the Department of Fish and Wildlife would allow him to use a disabled archer's permit and crossbow instead if a form were completed by his physician. *Id.*

At his April 26, 2017 OT visit, petitioner reported improvement of shoulder pain and continued resistance exercises with a bottle of water. Pet. Ex. 2 at 494. On May 2, 2017, petitioner presented with numbness in the ulnar distribution of his left hand, resolved forearm and upper arm pain, and pain improving in his left shoulder. Pet. Ex. 2 at 505. He described discomfort in his shoulder. *Id.* He attended OT on May 8, May 15, May 30, and June 12, at which point he was discharged. *Id.* at 509, 515, 522, 532-33.

On June 28, 2017, petitioner again presented with abdominal pain similar to what he had experienced in the past. Pet. Ex. 2 at 539-40. As he had done in the past, petitioner reported being under stress because his mom had pancreatic cancer. *Id.*

At a telemedicine appointment on August 29, 2017, petitioner reported that he had stopped taking Neurontin since his last visit, was doing curls with weights, and his shoulder was "doing fine." Pet. Ex. 3 at 27. However, he continued to have a "twinge of pain" in his shoulder when raising his arm overhead. *Id.* The two fingertips on his left hand were still numb, and his small finger still fell asleep with use of his hand. *Id.*

Petitioner presented with abdominal pain in September and October of 2017. Pet. Ex. 3 at 32, 51,142, 144, 200.

At a December 14, 2017 visit, petitioner reported that his symptoms were much improved overall, although he still had some numbness in his fingertips. Pet. Ex. 3 at 320. He again declined EMG and MRI testing or steroids. *Id.* He inquired if anything could be done for the numbness in his fingers. He was given a referral for a second opinion. *Id.*

Petitioner presented for a second neurological opinion with Dr. Nastaran Rafiei on December 22, 2017 reporting continued numbness in his fingers and weakness of the left arm. Pet. Ex. 3 at 327, 330. Dr. Rafiei believed petitioner's symptoms "could be due to a Parsonage Turner with patchy involvement of brachial plexus but cannot not rule out other possibilities like cervical radiculopathy or compression neuropathy." *Id.* at 330. Petitioner reported a fear of needles and would not proceed with any treatment that involved needles. *Id.* at 331. Dr. Rafiei advised petitioner to contact her if he changed his mind. *Id.*

E. Petitioner's Affidavit

On March 15, 2018, petitioner filed his affidavit. Pet. Ex. 4. Petitioner's affidavit affirmed receipt of the Tdap vaccination on November 11, 2016, his diagnosis of Parsonage Turner Syndrome caused by the Tdap vaccination, and that he suffered residual effects from his injury in excess of six months. *Id.* at 1.

II. Issues to be Determined

Petitioner alleges that he suffered from both BN and SIRVA. *See* Motion. Respondent argues that because petitioner has BN, he could not have suffered from a SIRVA; further, because the onset of his BN was less than two days after receipt of the vaccine, he did not suffer from a Table vaccine related BN injury. *See generally* Response. Thus, petitioner must

demonstrate that the vaccine was the cause-in-fact of one or both of his injuries to be entitled to compensation. *See Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 351 (Sept. 29, 2011) ("To be compensated under the Vaccine Act, petitioners must prove that *an* injury was caused by a vaccine listed on the Vaccine Injury Table") (emphasis added).

III. Expert Reports

A. Petitioner's Expert, Dr. Naveed Natanzi

1. Qualifications

Petitioner filed an expert report from Dr. Naveed Natanzi. *See* Pet. Ex. 6. Dr. Natanzi obtained his medical degree from Western University of Health Sciences and completed his residency at University of California, Irvine. Pet. Ex. 25 at 1-2. He is board certified in physical medicine and rehabilitation and founded the Regenerative Sports and Spine Institute in Sherman Oaks, California. *Id.* at 1.

2. Dr. Natanzi's Report

In Dr. Natanzi's opinion, petitioner suffered from both a SIRVA and BN injury as a result of the Tdap vaccine he received on November 11, 2016.

Dr. Natanzi submitted that petitioner's "presentation clearly meets the accepted temporal relationship for a SIRVA diagnosis" with pain or dysfunction within 48 hours after vaccination. Pet. Ex. 6 at 7. Further, petitioner felt a protracted course of pain that began almost immediately after the injection, attributable to overpenetration of the vaccine needle resulting in contact with the subacromial bursa and/or rotator cuff. *Id.*[14, 15]

In addition to onset within 48 hours of vaccination, Dr. Natanzi explained that those with SIRVA commonly present with symptoms and physical signs, such as a limited range of motion in the rotator cuff muscles, weakness due to pain of the rotator cuff muscles, and tenderness at the rotator cuff. Pet. Ex. 6 at 9-10. Clinical signs of capsulitis, tendinitis, and impingement may also be seen with SIRVA. *Id.* at 10.

Dr. Natanzi pointed to specific entries in the medical record regarding the onset of petitioner's pain to satisfy the SIRVA requirements. Pet. Ex. 6 at 7. First, on November 12, 2016,

[14] Dr. Natanzi wrote that this was caused by petitioner being seated while the vaccine administrator was standing when the vaccine was administered. This information is not contained in the medical record or petitioner's affidavit. It appears that Dr. Natanzi spoke with petitioner at some point, and this may have been discussed, but Dr. Natanzi does not reference where this information came from.

[15] Dr. Natanzi noted that the exact location of vaccination on the deltoid was not recorded, no imaging or ultrasound was used to confirm needle placement, and there was no report of type or length of needle used. Pet. Ex. 6 at 7. Petitioner denied strenuous or atypical work or injury to the neck or shoulder in the days preceding the vaccination. *Id.* In the subsequent days, weeks, and months, petitioner felt numbness, pain, and limited functional use of the left upper limb with sluggish progressive improvement of his symptoms. *Id.*

Drs. Szema and Ceponiene documented that petitioner experienced pain following receipt of a vaccination on November 11, 2016. *Id.*; Pet. Ex. 2 at 212, 221. Second, on November 15, 2016, Dr. Issakhanian documented that petitioner "almost immediately had some pain at the site of injection." Pet. Ex. 6 at 7; Pet. Ex. 2 at 297. Third, on December 22, 2017, Dr. Rafiei documented petitioner's belief that all his symptoms started after the Tdap vaccine because he "almost immediately" had pain at the injection site. Pet. Ex. 6 at 7; Pet. Ex. 3 at 327. Finally, petitioner reported to Dr. Natanzi that his immediate post-vaccination pain was a 4/10, when he usually experienced no pain after receiving a vaccine. Pet. Ex. 6 at 7.

Dr. Natanzi submitted that the medical records also support a structural injury of the shoulder consistent with SIRVA. Pet. Ex. 6 at 10. He noted that Dr. Issakhanian expressed concern that petitioner take care to avoid frozen shoulder. *Id.*; Pet. Ex. 2 at 321. Petitioner's OT record from June 12, 2017 documented pain with overhead activities characteristic of rotator cuff mediated pain. Pet. Ex. 6 at 10; Pet. Ex. 3 at 5. Further, petitioner reported difficulty and pain when blow drying his hair, which requires flexion and internal/external rotation of the arm, reproducing orthopedic maneuvers used to test for strain and impingement of the rotator cuff. Pet. Ex. 6 at 10; Pet. Ex. 3 at 27. Dr. Natanzi concluded that, even though a complete musculoskeletal examination was not conducted on petitioner and an MRI was not done, within a reasonable degree of medical probability, there were signs of rotator cuff mediated pain suggestive of SIRVA. Pet. Ex. 6 at 10.

Dr. Natanzi further opined that petitioner suffered BN as a result of the Tdap vaccine. Pet. Ex. 6 at 8. Dr. Natanzi acknowledged that the Table recognizes BN injury from a tetanus vaccine when onset occurs within 2-28 days of vaccination; he conceded that petitioner's onset was 15.5 hours after vaccination. *Id.* However, Dr. Natanzi submitted that when petitioner received his vaccine at 9am the morning of November 11, 2016, his "initial atypical pain" was related to SIRVA—not BN. *Id.* When he awoke around 12:30am or roughly 15.5 hours after vaccination with severe intense pain, weakness, numbness and tingling, that was BN. *Id.* Dr. Natanzi submitted that in speaking with petitioner, petitioner expressed his pain as a 4/10 following receipt of the vaccine but a 15/10 when it awoke him from sleep 15.5 hours later. *Id.* Accordingly, Dr. Natanzi concluded that petitioner's initial pain immediately following the vaccine was related to SIRVA, while the intense 15/10 pain that awoke petitioner from sleep was BN. *Id.*

Noting that the onset of petitioner's BN pain was 32 hours short of the timeframe contained in the Vaccine Injury Table, Dr. Natanzi argued that the timeframes on the Table are merely guidelines. Pet. Ex. 6 at 8; *see* 42 C.F.R. § 100.3. He explained that every person's body responds differently to any given stimulus. *Id.* For example, some people may swell and itch immediately after a mosquito bite, while others barely notice any symptoms. *Id.*

To support his opinion that petitioner suffered BN within 15.5 hours of the Tdap vaccine, Dr. Natanzi submitted several case studies in which the onset of BN was less than two days after vaccine. Pet. Ex. 6 at 8. In *Weintraub & Chia*, onset of paralytic BN was 17 hours after a swine flu vaccine. *Id.*; Pet. Ex. 21.[16] In *Taras* and *Beredjiklian*, onset of radial palsy, which is similar to

[16] M. I. Weintraub, M.D & D. T. S. Chia, M.D., *Paralytic Brachial Neuritis After Swine Flu Vaccination*, 34 ARCHIVES OF NEUROLOGY 518 (1977), filed as "Pet. Ex. 21."

BN in pathophysiology, occurred 12 hours and 16 hours after flu vaccination, respectively. Pet. Ex. 6 at 8; Pet. Ex. 23;[17] Pet. Ex. 24.[18]

Dr. Natanzi also relied on an article in which the authors reviewed FEDRA (the Adverse Reaction Data of the Spanish Pharmacovigilance System database) for the risk of shoulder injuries following vaccination. Pet. Ex. 16.[19] They found "6 in 8 FEDRA patients complained of increasing severity pain starting within the first 24 [hours] or few days (4-7 days) post-vaccination." *Id*. at 3. They further determined that "the patients had inmmediate (sic) pain or pain arising within the first 24 h post-vaccination in 81.1% of cases." *Id*. A table contained therein showed onset of bursitis only "a few hours" after PPV vaccine, and onset of tenosynovitis only "a few hours" after flu vaccination. *Id*. at 2 Table 1. The authors included a second table in the article, documenting cases of shoulder injuries related to the administration of vaccines published in medical literature. *Id*. at 4 Table 2. Included were 13 cases of bursitis, tendonitis, and torn rotator cuff with immediate onset or onset within 24 hours following flu vaccines and TD vaccines. *Id*.

Additionally, Dr. Natanzi relied on *Miller et. al*, which described BN as most commonly presenting in males between the ages of 20-60 with characteristic awaking from sleep with pain like petitioner. Pet. Ex. 6 at 8; Pet. Ex. 18.[20] Further, case reports document BN following a variety of vaccinations, presenting with a period of severe and intense pain for days to weeks that improves and is followed by a period of significant weakness. *Id.* at 8-9. EMG testing typically shows positive signs of acute denervation within three weeks with weakness present in the supraspinatus, infraspinatus and/or deltoid muscles, and occasionally the bicep muscles. *Id.* At 9.

Dr. Natanzi opined that petitioner's presentation was consistent with what is seen in BN. Petitioner developed severe pain, numbness, and tingling with weakness of the deltoid muscle, as described by Dr. Szema in the ER. Pet. Ex. 6 at 9; Pet. Ex. 2 at 221. He was diagnosed with possible BN that gradually improved with ongoing persistent neurological symptoms of weakness and paresthesia. Pet. Ex. 6 at 9; Pet. Ex. 2 at 218, 296, 483. On April 25, 2017, Dr. Issakhanian documented that petitioner's pain subsided, but the neurological symptoms of weakness and paresthesia persisted. Pet. Ex. 6 at 9; Pet. Ex. 2 at 482. Similar findings of a pins-and-needles sensation in petitioner's hands and fingers were present at his visit over 13 months after vaccination in December of 2017 when Dr. Rafiei noted improvement of shoulder pain but lingering numbness and weakness and diminished sensation in his left hand. Pet. Ex. 6 at 9; Pet. Ex. 3 at 327, 330. Even though an EMG was not performed, Dr. Natanzi opined that "there [was] enough clear-cut clinical data to make the diagnosis without it. This notion is further supported by the clinical suspicion of BN by nearly all treating providers, including Drs. Szema, Ceponiene, Issakhanian, and Rafiei." Pet. Ex. 6 at 9.

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[17] Beredjiklian, M.D. et al., *supra* note 4.

[18] John S. Taras, M.D. & Kenneth W. Donohue, M.D., *Radial Nerve Motor Palsy Following Seasonal Influenza Vaccination: A Case Report*, 23 J. OF SURGICAL ORTHOPAEDIC ADVANCES 42 (2014), filed as "Pet. Ex. 24."

[19] L.H. Martín Arias et al., *Risk of Bursitis and Other Injuries and Dysfunctions of the Shoulder Following Vaccinations*, 35 VACCINE 4870 (2017), filed as "Pet. Ex. 16."

[20] Miller, M.D. et al., *supra* note 3.

Dr. Natanzi concluded that a causal relationship existed between the Tdap vaccine and the development of petitioner's BN, given the acute onset of pain that progressively improved, followed by a protracted course of neurological symptoms like weakness and numbness, and the characteristic epidemiologic profile. Pet. Ex. 6 at 9. Petitioner's onset of symptoms was "in line with a BN diagnosis," even though his onset occurred sooner than what has been documented in other BN cases and on the Vaccine Injury Table. *Id.* at 8. In Dr. Natanzi's opinion, petitioner was injured by the vaccination and his clinical course was "highly suggestive of BN." *Id.*

Dr. Natanzi further concluded that petitioner had an overlap of symptoms of SIRVA and BN, but with symptoms exclusive to both injuries. Pet. Ex. 6 at 10. Acute severe onset of pain with accompanying numbness, marked weakness, and subsequent protracted course of neurologic deficits in the hand were related to BN—not SIRVA. *Id.* In contrast, the immediate discomfort following vaccination and signs and symptoms of what seem to be persistent rotator cuff mediated pain was suggestive of a SIRVA—not BN. *Id.* Both were caused by the Tdap vaccine administered on November 11, 2016. *Id.*

B. Respondent's Expert, Dr. Thomas P. Leist

1. Qualifications

Respondent filed an expert report from Dr. Thomas P. Leist. *See* Resp. Ex. A. Dr. Leist obtained his medical degree from University of Miami and completed his residency at Cornell Medical Center/Sloan Kettering Memorial Cancer Center. Resp. Ex. B at 1. He is board certified in psychiatry and neurology. *Id.* Dr. Leist specializes in the field of neuroimmunology and directs a clinical program in that neurologic subspecialty. Resp. Ex. A at 1. He has been a Professor of Neurology at Thomas Jefferson University since 2014. Resp. Ex. B at 1.

2. Dr. Leist's Report

Dr. Leist disagreed that petitioner suffered either SIRVA or BN as a result of his Tdap vaccine. Resp. Ex. A at 5-6. Dr. Leist opined that the shoulder pain petitioner experienced soon after the vaccination may have been due to a localized reaction to the Tdap vaccine, which is common according to the CDC Pink Book, or the onset of his neurological condition "coincidentally occurring at the time soon after vaccination." *Id.* at 4-6; *see* Resp. Ex. A, Tab 5.

According to Dr. Leist, the symptoms associated with SIRVA include pain, reduced range of motion limited to the vaccinated shoulder, and the absence of another condition that would explain the symptoms, such as BN or cervical radiculopathy. Resp. Ex. A at 5; Pet. Ex. 11.[21] Even though petitioner had an onset of symptoms within 48 hours of receipt of the Tdap vaccine as required by the Vaccine Table for SIRVA injury, his symptoms were not consistent with SIRVA but more likely a local vaccine reaction or the onset of his neurological condition. Resp. Ex. A at 6; *see* 42 C.F.R. § 100.3.

[21] S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049, 8051-52 (2010), filed as "Pet. Ex. 11."

Dr. Leist opined that petitioner developed "a temporary self-resolving swelling in the area of the administration of Tdap" vaccine, which occurs in about one fifth of patients. Resp. Ex. A at 8. The CDC Pink Book notes local reactions, including erythema, induration, and pain at the injection site following diphtheria and tetanus toxoid vaccination to be common. *Id.* at 4; Resp. Ex. A, Tab 5. Additionally, the prescribing information for Adacel (the Tdap vaccine received by petitioner) documents that about two thirds of the individuals in trials reported pain at the injection site; almost 25% of the patients had redness at the injection site; and more than 20% experienced swelling. *Id.*

Dr. Leist agreed that petitioner suffers from BN but disagreed it was the result of the Tdap vaccine. Resp. Ex. A at 6. He noted that Dr. Szema found weakness on examination at around 2am on November 12, 2016 – roughly 17 hours after vaccination. Pet. Ex. 2 at 211-14. However, that weakness was of the muscles supplied by the radial, median ulnar distribution, not the axillary nerve. *Id*. at 214. Further, ultrasound of petitioner's upper arm was normal. Resp. Ex. A at 6.[22] According to Dr. Leist, there is "no recognized mechanism by which local injection-related injury can cause relatively immediate distant de novo neurologic dysfunction." *Id*. at 5. He added that Dr. Szema wrote that she did "not suspect axillary nerve injury given patient able to hold arm in abduction and lack of numbness in the shoulder." *Id.*; Pet. Ex. 2 at 218.

Dr. Leist took issue with the characterization that the 2-28 day timeframe for BN following tetanus vaccine set forth in the Vaccine Injury Table was merely a guideline, submitting that the onset within 2-28 days "takes into consideration the minimal, biologically plausible time interval necessary for a putative vaccine relate (sic) immune response to occur and to cause brachial neuritis, which usually presents with abrupt onset of generally unilateral shoulder pain." Resp. Ex. A at 6. The initial pain is then followed by "progressive neurologic deficits over a course of a few days to weeks with progressive weakness, reflex changes, and sensory abnormalities involving the shoulder girdle musculature and proximal upper arms." *Id.* BN is thought to be caused by either a viral illness that affects the brachial plexus or an immune response against a virus or a viral antigen. *Id.*; Resp. Ex. A, Tab 3.[23] To that end, Dr. Leist argued that petitioner was prescribed Cipro for a gastrointestinal virus at the time he received the Tdap vaccine which was the cause of his BN; the timing of the Tdap vaccine was merely a coincidence. Resp. Ex. A at 2, 4.

Dr. Leist relied on *Rowhani-Rahbar et al.* to show that, at minimum, two days are necessary for a "vaccine-induced immune response cross-reactive with nerve cells of the brachial plexus to occur." Resp. Ex. A at 6; Resp. Ex. A, Tab 4.[24] He conceded the study did not specifically include BN, but claimed that it "propose[d]" a 2-42 day interval for the development of neurologic illness following vaccination as biologically plausible. *Id.* Further, Dr. Leist noted that there was no

[22] After careful review of the medical records, it appears that a diagnostic ultrasound of petitioner's upper arm was not performed. The only ultrasounds documented in the records were part of petitioner's OT treatment. *See* Pet. Ex. 2 at 352, 374, 380, 386, 399-400, 406-07, 415-16, 422-23, 435-36, 441, 450, 456, 463, 495, 504, 510, 516, 523, 530; Pet. Ex. 3 at 4. The "normal" ultrasound to which Dr. Leist referred is unclear since he did not provide a citation to the medical records.

[23] Joseph H. Feinberg, M.D. & Jeffrey Radecki, M.D., *Parsonage-Turner Syndrome*, 6 HOSPITAL FOR SPECIAL SURGERY 199 (2010), filed as "Resp. Ex. A, Tab 3."

[24] Ali Rowhani-Rahbar, *Biologically Plausible and Evidence-Based Risk Intervals in Immunization Safety Research*, 31 VACCINE 271 (2012), filed as "Resp. Ex. A, Tab 4."

indication that petitioner suffered an anaphylactic reaction before he went to bed on the evening of November 11, 2016. Resp. Ex. A at 7. Thus, the 15-16-hour onset seen here is too short to implicate the Tdap vaccine as the cause of petitioner's BN. *Id.* at 6.

Further, Dr. Leist referenced petitioner's medical records including the ED record for November 12, 2016, in which Dr. Szema documented weakness involving several peripheral nerves, the left brachial plexus in a widespread fashion, and nerve roots likely from C5/C6 to T1. Resp. Ex. A at 7. Dr. Issakhanian's notes on November 15, 2016, which documented that the "distribution of numbness, weakness goes beyond a single nerve injury or even a radiculopathy." *Id.*; Pet. Ex. 2 at 300. Dr. Rafiei's December 22, 2017 record which documented "mild weakness of mainly proximal LUE in C4-C6 myotomes" and "numbness mainly in left C8 versus ulnar dermatome" with cervical radiculopathy possible. Resp. Ex. A at 7; Pet. Ex. 3 at 330. Dr. Leist then concluded that based on these records, cervical radiculopathy could not be excluded. Resp. Ex. A at 7. He added that the documented findings between November 12, 2016 and December 22, 2017 showed little difference, petitioner's symptoms apparently did not worsen between 2-28 days following the administration of the Tdap vaccine, which was unusual for BN because that is the timeframe listed on the Table for the onset of BN symptoms following a Tdap vaccination. *Id.* at 7-8.

Dr. Leist opined that the "constellation of neurologic symptoms" petitioner presented with 15-16 hours after the Tdap vaccine were not consistent with SIRVA, based on symptoms, or with BN, based on timing. Resp. Ex. A at 8. Rather, petitioner had a three-week gastrointestinal issue for which he was seen on November 11, 2016, which could have been the infection that triggered his injury. *Id.* Further, Dr. Leist opined that petitioner developed common swelling at the injection site, but the Tdap vaccine did not cause petitioner's injury and did not lead to enduring aggravation of a pre-existing injury. *Id.* It is unclear what pre-existing injury Dr. Leist was referring to as there is no record of petitioner having any pre-existing left shoulder injury.

IV. Discussion

A. Legal Standard

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities

to establish a logical sequence of cause and effect." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. *Id.* at 1325-26.

In particular, a petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *see also Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. *Shyface*, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case." *Flores v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 157, 162-63 (2014); *see also Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question"); *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief"); *Pafford*, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations").

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). The process for making determinations in Vaccine Program cases regarding factual issues begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are generally considered to be more trustworthy. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Human Servs.*, 993 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that *Cucuras* does not stand for proposition that medical records are presumptively accurate and complete). While not presumed to be complete and accurate, medical records made while seeking treatment are generally afforded more weight than statements made by petitioner after-the-fact. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014). Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health &*

Human Servs., 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining facts such as the onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs.*, No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs*., No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"); *see also Burns*, 3 F.3d at 417 (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

There are situations in which compelling oral testimony may be more persuasive than written records. *See Campbell*, 69 Fed. Cl. at 779 (2006). When witness testimony contradicts medical records, such testimony must be consistent, clear, cogent, and compelling to be persuasive. *See Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (vacated on other grounds, *Sanchez by & through Sanchez v. Sec'y of Health & Human Servs*., No. 2019-1753, 2020 WL 1685554 (Fed. Cir. 2020), *review denied, Sanchez by & through Sanchez v. Sec'y of Health & Human Servs*., 152 Fed. Cl. 782 (2021)) (quoting *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998)); *see, e.g., Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs*., No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). Special masters may also consider other types of evidence, such as unsworn statements, on the grounds that the Vaccine Program was designed to have "flexible and informal standards of admissibility of evidence." 42 U.S.C. § 300aa-12(d)(2)(B); *see also Munn v. Sec'y of Health & Human Servs*., 970 F.2d 863, 873 (Fed. Cir. 1992).

On the whole, a special master's fact findings are to be upheld when the special master's evaluation is evidence-based and not wholly implausible. *See Colon v. Sec'y of Health & Human Servs.*, 156 Fed. Cl. 534 (2021).

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano*, 440 F.3d at 1319-20. Where petitioner does not allege that he suffered a Table Injury, he must prove that the vaccine he received caused his injury. *See generally* Motion. To do so, petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence"); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

D. Analysis of *Althen* Prongs

In his Motion for Ruling on the Record, petitioner alleges that he suffered both a SIRVA and a BN injury. *See* Motion at 1. Respondent opposed petitioner's claim that he suffered a SIRVA injury and only submitted arguments against *Althen* Prongs II and III regarding petitioner's claim of BN injury. Response at 1. Petitioner need only carry his burden of an injury alleged to be entitled to compensation. *See Veryzer*, 100 Fed. Cl. at 351 ("To be compensated under the Vaccine Act, petitioners must prove that *an* injury was caused by a vaccine listed on the Vaccine Injury Table") (emphasis added); *Knudsen*, 35 F.3d at 550 (stating that petitioners "need not explain all *other* symptoms or injuries by reference to the [] vaccination"). Because I find that petitioner suffered a BN injury as a result of his receipt of the Tdap vaccine, only BN is addressed below.

Due to the onset of petitioner's symptoms of BN between 15 and 16 hours after the Tdap vaccine, rather than within the 2-28 day time period set forth in the Vaccine Table, petitioner's claim for BN injury is classified as an "off-Table" claim. Therefore, petitioner must show by preponderant evidence that his injury resulted from the vaccination at issue. *Capizzano*, 440 F.3d at 1320. Doing so shifts the burden to respondent to show that the injury was caused by factors unrelated to the vaccination. *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013).

1. Petitioner has Advanced a Sound and Reliable Medical Theory

The first *Althen* Prong requires that petitioner provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this Prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). This standard was recently clarified by the Federal Circuit. *See Boatmon*, 941 F.3d at 1359-60 (stating that the correct standard for *Althen* Prong one is "reputable" and "sound and reliable"—not a "lower reasonable standard" (internal

quotations omitted)). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

Respondent submitted that "for purposes of petitioner's motion in this case, he would not challenge the alleged causal connection between the Tdap vaccination and brachial neuritis" and directed his arguments exclusively to Prongs II and III. Response at 13, ECF No. 48.

Therefore, because the Vaccine Program recognizes that Tdap can cause BN and because respondent presented no argument to the contrary, Prong I is satisfied.

2. Petitioner has Provided a Logical Connection and Demonstrated a Proximal Temporal Relationship satisfying Prongs II and III.

The second *Althen* Prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccinations can cause the injury, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). A sound and reliable "medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375). Petitioner is not, however, required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes").

In evaluating whether Prong II is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'" (quoting *Althen*, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. *Cucuras*, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1325. Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. *Id.* at 1325-26.

To satisfy the third *Althen* Prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the

proximate temporal relationship Prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this Prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness").

Respondent agreed that petitioner suffered from BN but argued that the onset of his symptoms was too soon after vaccination to implicate the vaccine as the cause and therefore his BN was unrelated to the Tdap vaccine he received. Response at 14-16, 21. Accordingly, respondent's arguments regarding both Prongs II and III revolve around timing. Thus, the two Prongs are more easily addressed together.

i. The Parties' Arguments

Petitioner argued that he suffered from BN pursuant to the Qualifications and Aids to interpretation ("QAI"), which defines BN as "dysfunction limited to the upper extremity nerve plexus (i.e. its trunks, divisions, or cords)." 42 C.F.R. 100.3(c)(6) (2017). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. *Id.* The pain is typically followed in days or weeks by weakness in the affected upper extremity muscle groups. *Id*. Sensory loss may accompany the motor deficits but is generally a less notable clinical feature. *Id*. Atrophy of the affected muscles may occur. *Id*. Further, up to 15% of BN cases have been reported to be after vaccination. Motion at 5. Specifically, immune mediated demyelinating responses to tetanus toxoid are believed to cause post-vaccination BN. Pet. Ex. 20 at 2.[25]

Petitioner further argued that he showed by a preponderance of evidence that the Tdap vaccine was the cause in fact of his BN, even though his onset was outside the 2 to 28 days listed on the Vaccine Injury Table. Motion at 6. He claimed that onset 15 hours post-vaccination is still "within a medically acceptable timeframe." *Id.*

Dr. Natanzi submitted that no two individuals are the same in their immunologic responses, resulting in outliers to the Table's expected timeframe of 2-28 days for onset of BN after Tdap vaccination. Motion at 6; Pet. Ex. 6 at 8. Petitioner relied on case studies that reported onset of nerve injury symptoms in less than 2 days and between 16-17 hours after vaccination. Pet. Ex. 21;[26] Pet. Ex. 23;[27] Pet. Ex. 24.[28] Based on the findings in those studies, Petitioner argued that symptom onset outside the timeframe set forth in the Vaccine Injury Table is still consistent with post-vaccination BN. Motion at 7.

Further, petitioner relied on the opinions of his treating physicians as evidence that his symptoms satisfy the criteria for BN following Tdap vaccine. In the emergency room on November 12, 2016, Dr. Szema noted concern for BN, documenting weakness of his left radial, median, and

[25] Taras et al., *supra* note 7.
[26] Weintraub & Chia, *supra* note 16.
[27] Beredjiklian, M.D. et al., *supra* note 4.
[28] Taras & Donohue, *supra* note 18.

ulnar nerves. Motion at 7; Pet. Ex. 2 at 214. On November 15, 2016, Dr. Issakhanian and her colleague suspected BN and agreed that petitioner's injury went beyond a single nerve injury. Motion at 7; Pet. Ex. 2 at 300. Dr. Issakhanian maintained her assessment that petitioner had BN and treated him for that injury over the next year. Motion at 7. Further, petitioner sought a second opinion from Dr. Rafiei in December of 2017, who documented his symptoms as BN with "patchy involvement of the brachial plexus." Motion at 7-8; Pet. Ex. 3 at 330.

Respondent did not dispute that Tdap vaccine can cause BN, or that petitioner has BN, or that his onset of BN occurred after receipt of the Tdap vaccine. Rather, respondent argued that it is petitioner's burden to provide evidence establishing that the particular causation theory set forth by his expert, including the appropriate timeframe for onset of symptoms under the theory, applies specifically to petitioner. Response at 12-13, 16.

Respondent argued that the case studies relied on by petitioner to show onset of BN-like symptoms in less than two days after Tdap are insufficient to meet his burden. Response at 14. First, some of the studies relied on involved swine flu and influenza vaccines—not Tdap vaccines. *Id.* Second, of the case reports that studied potentially vaccine-caused BN, onset occurred in 3-7 days after vaccination. *Id.* at 14-15; *See* Pet. Ex. 19;[29] Pet. Ex. 20.[30] In those studies the timing of onset fell squarely within the Table's 2–28-day timeframe after vaccination. *Id.* Respondent further noted that one of the case reports submitted showed surgery, viral disease, infection, autoimmune mechanism, and immunization as precipitating factors of BN; and in 30-85% of cases, an "antecedent event" occurred 3-14 days prior to the initial onset of pain. Response at 15; Pet. Ex. 20 at 1.[31] Thus, none of the literature supports the proposed causal theory of an immune-mediated local demyelinating response to the tetanus toxoid component of Tdap, resulting in onset of symptoms within 15 hours. *Id.*

Respondent relied on Dr. Leist's opinion that the Table's 2-28-day timeframe takes into consideration the minimal biologically plausible time interval necessary for a vaccine-related immune response to occur and cause BN. Response at 15; Resp. Ex. A at 6. Respondent agreed with Dr. Natanzi that individuals respond differently with varying intensities of immunogenic response but submitted that biologically plausible limits exist for how quickly observable immunologic response can occur. Response at 15. The timeframe seen here—15-16 hours—is too short for a vaccine induced immune response to be cross reactive with nerve cells of the brachial plexus. *Id.*; Resp. Ex. A at 6; Resp. Ex. A, Tab 4.[32] To support this contention, respondent referred to petitioner's treating physician Dr. Ceponiene's record that demyelinating plexopathy was "unlikely given the immediate timeline post vaccination." Response at 15; Pet. Ex. 2 at 225.

Respondent concluded that 15 hours between receipt of the Tdap vaccine and observable weakness and neurological symptoms was simply too soon to ascribe causation to the vaccination under accepted theories of autoimmunity. Response at 15-16, citing *de Bazan*, 539 F.3d at 1352; *Moberly*, 592 F.3d at 1322.

[29] Shaikh et al., *supra* note 6.
[30] Taras et al., *supra* note 7.
[31] *Id.*
[32] Rowhani-Rahbar, *supra* note 24.

ii. Analysis of the Parties' Arguments

Petitioner argued that his presentation is consistent with both a SIRVA and BN. As stated above, petitioner need only carry his burden on an injury alleged to be entitled to compensation. *See Veryzer*, 100 Fed. Cl. at 351; *Knudsen*, 35 F.3d at 550. Because the BN claim is dispositive, only BN is being addressed.

Dr. Natanzi opined that petitioner's BN presented when he developed significant pain, weakness, tingling, and numbness that awoke him from sleep at 12:30am—roughly 15 hours post-vaccination—necessitating a visit to the ER. Pet. Ex. 2 at 212.

Petitioner's treaters, Dr. Szema, Dr. Issakhanian, and Dr. Rafiei, all associated petitioner's arm pain with the receipt of the Tdap vaccine and diagnosed him with symptoms induced by vaccination. In the ER, Dr. Szema referred to possible SIRVA or BN from vaccination. Pet. Ex. 2 at 218. In a follow up appointment, Dr. Wong documented the "primary encounter diagnosis" as an adverse drug reaction. *Id.* at 263. Dr. Issakhanian's assessment was left shoulder pain and arm weakness after Tdap vaccine and symptoms consistent with BN, potentially due to an autoimmune reaction to the Tdap vaccination. *Id.* at 300. Though cervical radiculopathy was mentioned during the course of treatment, it was referred to as "possible" and in the context of a brachial plexus injury—not as an alternative diagnosis. *Id*. Further, Dr. Issakhanian wrote "distribution of numbness, weakness goes beyond . . . a radiculopathy." *Id*. Petitioner's treating physicians specifically referenced involvement of more than one nerve, indicative of BN, not radiculopathy. *Id.*; Pet. Ex. 18 at 2.[33]

Though the arguments of the parties and their experts are expectedly contrary, the opinions of petitioner's treating physicians are consistent and carry significant weight.[34] Petitioner experienced the onset of severe pain approximately 15.5 hours after vaccination, waking him from sleep in the middle of the night and prompting an emergency room visit. Pet. Ex. 2 at 212-14. Those symptoms were determined to be neurologic in nature and involved more than one nerve, indicative of BN. *Id*. at 300.

Dr. Leist argued that petitioner had a gastrointestinal virus requiring a prescription for Cipro on the date of vaccination and that the gastrointestinal virus was the cause of his BN—not the Tdap vaccine. Resp. Ex. A at 2, 4. However, the contemporaneous medical records do not support a gastrointestinal virus or that Cipro was prescribed on November 11, 2016. Rather, the medical records show that Cipro was prescribed in December of 2015 and re-prescribed in January of 2016. Pet. Ex. 2 at 84, 94. The record for the date of the Tdap vaccine, November 11, 2016, however, lists Cipro as a discontinued medication. *Id.* at 201. Similarly, the record lists other medications "discontinued" as of November 11, 2016, suggesting that the record documented past medications that were no longer being prescribed on the date of vaccination. *Id*. at 97, 184, 201. Further, the records show that petitioner suffered repeated bouts of stomach issues both before and after the date of his vaccination typically attributed to stress—not infection. *See id.* at 182, 539.

[33] Miller, M.D. et al., *supra* note 3.

[34] Other cases in the Vaccine Program have noted that "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." *Paluck*, 786 F.3d at 1385 (quoting *Andreu*, 569 F.3d at 1375 (Fed. Cir. 2009)).

This was the case on November 11, 2016 as well. *Id*. at 189. The record from that appointment documented a normal examination, no neurological complaints, and no signs of fever. *Id*. at 184-85. Petitioner was noted to be "healthy adult" with "[N]o worrisome findings on xr." *Id.* at 183–87, 191-92. The subject Tdap was administered. *Id.* at 192.

The case studies submitted have shown onset of post-vaccination BN symptoms in less than 24 hours. Pet. Ex. 21;[35] Pet. Ex. 23;[36] Pet. Ex. 24.[37] In one case report, Drs. Weintraub and Chia described a 57-year-old healthy man who developed discomfort, pain, and weakness of both upper extremities within 17 hours after receipt of a swine flu vaccine. Pet. Ex. 21.[38] They noted that "[i]rrespective of the vaccine used in immunization, reactions occur and brachial neuritis is frequently seen." *Id.*

Another case report documented a 26-year-old physician who developed progressively worsening weakness over his distal left upper extremity within 16 hours after receipt of a flu vaccine. Pet. Ex. 23 at 1-2.[39] The authors noted that "[t]here are several reports of peripheral nerve injuries following intramuscular vaccine injection." *Id.* at 1. Further, while offering their support for routine flu vaccines for healthcare personnel, the authors acknowledged that "inadvertent injury may be inevitable" given the sheer volume of vaccines administered. *Id.* at 3.

Further, in another report by Drs. Taras and Donohue, a 26-year-old surgical resident developed symptoms within 12 to 16 hours after a flu vaccine, with "complete wrist drop with lack of digital extension over 3 to 4 hours" after vaccination. Pet. Ex. 24 at 1-2.[40] Although the authors did not explain the timing of the patient's symptoms, they noted that BN has been "linked to postvaccination neuropathy." *Id.* at 1. They also included a table in their report that listed tetanus toxoid as an "offending agent[]," after which post-injection neuropathy is "well-reported." *Id.* at 1, 2 at Figure 1.

Respondent argued that the case studies submitted by petitioner showing onset of BN-like symptoms within 12-17 hours following vaccination are inapplicable here because they involved swine flu and influenza vaccines rather than the Tdap vaccine. Response at 14-15. However, neither respondent or his expert explained how swine flu and/or influenza vaccine could cause BN-like injuries within 16-17 hours but a Tdap vaccine could not. Further, one of the case reports specifically listed tetanus toxoid as an "offending agent[]" known to be linked to postvaccination neuropathy. *See* Pet. Ex. 24 at 1, 2 at Figure 1.[41]

Further, it remains unclear in the literature whether vaccine placement or the antigen itself is to blame for development of BN following vaccination. *See* Pet. Ex. 23 at 3 ("[w]hether an injection injury to a peripheral nerve is caused by direct injury to the nerve or secondary to chemical insult is unclear. . . The imaging in this case study suggests that his nerve injury was

[35] Weintraub & Chia, *supra* note 16.
[36] Beredjiklian, M.D. et al., *supra* note 4.
[37] Taras & Donohue, *supra* note 18.
[38] Weintraub & Chia, *supra* note 16.
[39] Beredjiklian, M.D. et al., *supra* note 4.
[40] Taras & Donohue, *supra* note 18.
[41] *Id.*

caused by injection of the vaccination into the nerve sheath and not the nerve itself. . . The etiology of injury—direct trauma to the nerve versus indirect injury via an inflammatory process—remains unclear);[42] *see also* Pet. Ex. 16 at 1 (subdeltoid or subacromial bursitis and other lesions…may be related to antigens or adjuvants contained in the vaccines that would trigger an immune response or inflammatory condition. However, they are more likely to be the consequence of a poor injection technique.).[43] Thus, the type of vaccine may be less significant than the placement of the injection, causing direct trauma to the nerve versus indirect trauma via inflammatory process versus antigens contained in the vaccine that trigger an immune response or inflammatory condition irrespective of what that antigen is. But clearly, tetanus toxoid contained in the Tdap vaccine has been reported as the "offending agent" known to be linked to postvaccination neuropathy. Pet. Ex. 16 at 1;[44] Pet. Ex. 23 at 3;[45] Pet Ex. 24 at 1, 2 at Figure 1.[46]

The following facts in this case are undisputed: Petitioner was otherwise healthy with no prior shoulder injury or conditions and no prior cervical issues. Petitioner received a Tdap vaccine on November 11, 2016 and experienced arm pain. Pet. Ex. 2 at 192, 297. Roughly 15.5 hours later, petitioner was awoken from sleep due to severe pain, which resulted in an ER visit at around 1am. *Id*. at 212-14. His treating physicians believed that he suffered a possible SIRVA or BN as a result of the Tdap vaccine he received the previous morning. *Id.* at 218*; see also* Pet. Ex. 5. His BN progressed characteristically with pain, numbness, weakness, and tingling in his arm and hand. Pet. Ex. 2 at 300, 398, 416, 423. Throughout the months following vaccination, petitioner's severe pain subsided. Pet. Ex. 2 at 484. However, the sensory symptoms—the numbness and tingling in his arm and hand—remained. *Id.* While petitioner did not undergo MRI or EMG testing due to a long-professed fear of needles, neither petitioner nor respondent question that petitioner suffers from BN. Pet. Ex. 3 at 331; *see generally* Motion; Response.

Therefore, this case comes down to petitioner's onset of BN within 15.5 hours of his Tdap vaccine rather than 2-28 days after his Tdap vaccine as set forth in the Vaccine Table. Dr. Leist argued that the onset of petitioner's neurologic symptoms was coincidental because it was 15.5 hours rather than 2 days after vaccination, concluding that onset that soon after vaccination is not biologically possible. *See generally* Resp. Ex. A. However, the literature highlights that just like peripheral nerve injuries from improper administration of vaccinations vary in severity and type of injury and recovery, so does the onset of symptoms, with reports being as early as 12 -16 hours after vaccination. Pet. Ex. 23.[47] The literature submitted shows onset of symptoms in less than two days and as early as "a few hours" after vaccination. *See* Pet. Ex. 16 at 2-3,[48] which documented bursitis and tenosynovitis within "a few hours" after vaccination with PPV and flu vaccines, respectively; and 13 cases of bursitis, tendonitis, and tear of the rotator cuff that had an immediate onset or onset within 24 hours following flu vaccines and TD vaccines; *see also* Pet. Ex. 24,[49] a case report of a 26-year-old who began having symptoms of clumsiness and wrist drop within 12-

[42] Beredjiklian, M.D. et al., *supra* note 4.
[43] Arias et al., *supra* note 19.
[44] *Id.*
[45] Beredjiklian, M.D. et al., *supra* note 4.
[46] Taras & Donohue, *supra* note 18.
[47] Beredjiklian, M.D. et al., *supra* note 4.
[48] Arias et al., *supra* note 19.
[49] Taras & Donohue, *supra* note 18.

16 hours after receiving the flu vaccine. While the cause of BN is usually considered to be a postinfectious reaction or a reaction secondary to an allergic or hypersensitivity response, genetic predisposition has also been suggested. Pet. Ex. 21 at 1.[50] Further, according to the literature, it remains unclear whether the cause of peripheral nerve injuries from improper administration of vaccinations is from direct trauma to the nerve or from indirect injury via an inflammatory process. Pet. Ex. 23 at 3.[51]

The Vaccine Injury Table creates a presumption of causation where symptoms of BN manifest within 2-28 days after a Tdap vaccine. *See* 42 C.F.R. § 100.3(a); *Andreu*, 569 F.3d at 1374. To realize the purpose of the Vaccine Act, a timeframe had to be chosen. The timeframe of 2-28 days is appropriate because that is where the masses fall. However, not all people with BN injuries caused by the Tdap vaccine will fit squarely within that timeframe, and there will be outliers on either end of the spectrum. To illustrate this point, GBS is listed on the Table as a peripheral neurologic injury following influenza vaccine within 3 to 42 days, but cases have been determined to have symptom onset outside of the timeframe on the Table based on the totality of the circumstance in a particular case. *See Jewell v. Sec'y of Health & Human Servs*., No. 16–0670V, 2017 WL 7259139, at *3-4 (Fed. Cl. Spec. Mstr. Aug. 4, 2017) (citing to *Atanasoff et al.*—filed as Pet. Ex. 11[52] here—ruling for petitioner, although the medical records documented the onset of petitioner's symptoms as being outside the timeframe listed on the Table); *Spayde v. Sec'y of Health & Human Servs*., No. 16-1499V, 2021 WL 686682, at *18 (Fed. Cl. Spec. Mstr. Jan. 27, 2021) ("However, for non-Table claims, or causation-in-fact claims, special masters have generally found that petitioners are entitled to causation where onset occurs up to two months, eight weeks or 56 days, following the flu vaccination"); *see also Quackenbush-Baker v. Sec'y of Health & Human Servs*., No. 14–1000V, 2018 WL 1704523, at *20 (Fed. Cl. Spec. Mstr. Mar. 14, 2018) (ruling for petitioner where onset of the significant aggravation of multiple sclerosis was within 41 hours, rather than the 2-42 day timeframe listed on the Table); *but see Braun v. Sec'y of Health & Human Servs*., No. 16–1098V, 2018 WL 2375751, at *18 (Fed. Cl. Spec. Mstr. Apr. 24, 2018) (denying entitlement when onset of GBS was four months after flu vaccine but noting that "timing somewhat outside of the Table window might support a finding of causation in fact").

Further, although case reports contain specific individual case studies, they demonstrate what is possible—even if it is not regularly documented in the literature or shown by epidemiological evidence.[53] This is particularly true for vaccine related injuries, which are rare. The case reports submitted herein document the development of BN symptoms within 12-17 hours of receipt of a vaccine rather than the 2-28 days listed on the Vaccine Injury Table. Pet. Ex. 21;[54] Pet. Ex. 23;[55] Pet. Ex. 24.[56] Based on the literature submitted, BN associated with vaccination has

[50] Weintraub & Chia, *supra* note 16.
[51] Beredjiklian, M.D. et al., *supra* note 4.
[52] Atanasoff et al., *supra* note 21.
[53] It is worth noting once more that epidemiological evidence nor scientific certainty is required for a petitioner to carry their burden in proving that their injury was caused by a vaccine. *Capizzano*, 440 F.3d at 1325; *Bunting*, 931 F.2d at 873.
[54] Weintraub & Chia, *supra* note 16.
[55] Beredjiklian, M.D. et al., *supra* note 4.
[56] Taras & Donohue, *supra* note 18.

occurred in rare cases in less than two days following a vaccine and is consistent with the medical community's current understanding of BN.

Respondent offered no convincing alternative explanation for petitioner's injury. The suggestion that petitioner suffered from a gastrointestinal illness as the cause of his BN is defeated by the records before and after his vaccination showing that petitioner suffered from stomach issues related to stress and associated with major life events, such as here where he was caring for a sick parent. Pet. Ex. 2 at 182, 184, 539. Importantly, the contemporaneous medical record on the date of the Tdap vaccine show petitioner to be healthy, with no fever or other evidence of illness or active infection. *Id*. at 182-87, 201. Further, contrary to Dr. Leist's suggestion, petitioner was not prescribed Cipro on that date and Cipro was listed as a past medication along with others that had been discontinued. *See id*. at 182-205.

I find that petitioner has provided preponderant evidence of a logical sequence of cause and effect and a proximate temporal relationship based on expert opinion, literature, petitioner's clinical course, treating physician opinions, and a lack of evidence to support an alternative cause for his BN following his Tdap vaccination. Through his expert and the literature submitted, petitioner demonstrated that BN may on rare occasions have an onset within 15.5 hours after vaccination. Preponderant evidence supports that his BN was caused by the Tdap vaccine he received on November 11, 2016.

Thus, I find that petitioner has demonstrated that the Tdap vaccine was the cause-in-fact of his BN injury, and he is entitled to compensation.

V. Conclusion

Upon careful evaluation of all the evidence submitted in this matter—including the medical records, expert reports, and medical literature—I conclude that petitioner has shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. A separate damages order will issue.

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master